K013546

NOV 21 2001

510(k) Summary
Bionx Implants Inc.
1.5mm Bone Fixation Kit

Submitter's Name, Address, Telephone Number, and Contact Person

Bionx Implants, Inc.
1777 Sentry Parkway West
Gwynedd Hall, Suite 400
Blue Bell, PA 19422

Contacts: Gerard S. Carlozzi
President and CEO
Phone: (215) 643-5000
Facsimile: (215) 653-0984

Bionx Implants Ltd.
Tuija Annala
Director, Quality and Regulatory Affairs
P.O.Box 3
FIN-33721 Tampere
Finland, Europe
Phone: 358-3-316 5600
Facsimile: 358-3-316 5629

Date prepared: October 9th, 2001

Name of the device:

A.	Trade or Proprietary Name:	1.5mm Bone Fixation Kit
B.	Common Name:	Absorbable Bone Fixation Nail
C.	Classification Name:	Bone Fixation Nail
D.	Device Product Code:	MAI and HWC

Predicate Device:

1. Bionx Implants, Inc. SmartNail (K993074)
2. Bionx Implants, Inc. 1.5mm Bone Fixation Kit (K012000)

Intended Use:

Properly used, in the presence of adequate immobilization, 1.5mm Bone Fixation Kit is intended for use in the fixation of fragments of fractured non-load bearing bones, osteotomies and arthrodeses, for example in the fixation of apical fragments, osteochondral fragments and cancellous/non-load bearing fragments.

1.5mm Bone Fixation Kit is not intended for use in and is contraindicated for: 1) Fractures and osteotomies of cortical bone (except cortical bones of the foot and the hand), 2) Fractures and osteotomies in weight bearing cancellous bone, 3) Situations where internal fixation is otherwise contraindicated, e.g., active or potential infection and where patient co-operation cannot be guaranteed (e.g. alcoholism), 4) Treatment of physeal fractures in children, because the effect of the implant upon the healing of growth plate has not been tested clinically.

Device Description:

The device description of the 1.5mm Bone Fixation Kit is as follows.

- The implants are composed of poly-L/D-lactide copolymer. This is the very same raw material with SmartNail (K993074) and 1.5mm Bone Fixation Kit (K012000)
- Lengths of implants are 14, 16, 18, 20 and 25 mm.
- Diameter of implants is 1.5mm. This is identical with SmartNail (K993074) and 1.5mm Bone Fixation Kit (K012000)
- Shelf life is same with SmartNail™ and 1.5mm Bone Fixation Kit (K012000).
- Implants and single use, sterile, disposable instruments are packed into blister, which is sealed with the Tyvek® lid. Blister with Tyvek® lid is packed into aluminium foil pouch and sealed.

The modifications are:

- Amendment of new length, 14mm implant, into product line.
- Modified design accordingly.

Substantial Equivalence:

Bionx Implants Inc. 1.5mm Bone Fixation Kit is substantially equivalent to the cleared Bionx Implants Inc. SmartNail (K993074) and 1.5mm Bone Fixation Kit (K012000). This amendment of one new length with little change in design does not raise any new concerns of safety and efficacy of the implant. This modification has no effect on pull-out properties of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2001

Mrs. Tuija Annala
Director, Quality and Regulatory Affairs
Bionx Implants, Ltd.
Hermiankatu 6-8 L
Tampere, Finland

Re: K013546
Trade/Device Name: 1.5mm Bone Fixation Kit
Regulation Number: 21 CFR §888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC and MAI
Dated: October 8, 2001
Received: October 24, 2001

Dear Mrs. Annala:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K013546 NOV 21 2001

Device Name: **1.5mm Bone Fixation Kit**

Indications for Use:

1.5mm Bone Fixation Kit is intended for use in the fixation of fragments of fractured non-load bearing bones, osteotomies and arthrodeses, for example in the fixation of apical fragments, osteochondral fragments and cancellous/non-load bearing fragments.

1.5mm Bone Fixation Kit is not intended for use in and is contraindicated for: 1) Fractures and osteotomies of cortical bone (except cortical bones of the foot and the hand), 2) Fractures and osteotomies in weight bearing cancellous bone, 3) Situations where internal fixation is otherwise contraindicated, e.g., active or potential infection and where patient co-operation cannot be guaranteed (e.g. alcoholism), 4) Treatment of physeal fractures in children, because the effect of 1.5mm Bone Fixation Kit upon the healing of growth plate has not been tested clinically.

(Please do not write below this line – continue on another page is needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)